UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,336	12/01/2004	Philip John Birch	117-524	3696

23117 7590 10/14/2008

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
10/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/508,336	BIRCH ET AL.	
	Examiner	Art Unit	
	UMAMAHESWARI RAMACHANDRAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,38,39,41,48-52 and 67-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 38, 39, 41, 48-52, 67-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/10/2008, 9/10/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/10/2008 has been entered.

Claims 48, 49 and 68 have been amended and claims 16-27, 40, 42-47, 53-66 have been cancelled. Claims 1-15, 38, 39, 41, 48-52, 67-71 are currently pending and are being examined on the merits herein.

Response to Remarks

Claims 1-15, 38-39, 41, 48-52, 67-69 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Eriksen et al. (Applicant-cited reference on IDS: Eriksen, J. et al. *J. Pharm. Pharmacol.* **1989**, *41*, 803-805), in view of Watts et al. (Applicant-cited reference on IDS: WO 98/47535), Reich et al. (Reich, I., et al. "Tonicity, Osmoticity, Osmolality and Osmolarity" Remington: The Science and Practice or Pharmacy, Nineteenth Edition, Volume 1. Easton, PA: Mack, **1995**. pp. 613-615), and Nairn (Nairn, J. G. Solutions, Emulsions, Suspensions and Extracts" Remington: The Science and Practice or Pharmacy, Nineteenth Edition, Volume 2. Easton, PA: Mack, **1995**. p. 1502). The rejection is maintained. Applicant's arguments are addressed below. The rejection of claims 16 and 53-59 under 35 U.S.C. 103(a) as being unpatentable over Eriksen et al. (Applicant-cited reference on IDS: Eriksen, J. et al. *J. Pharm. Pharmacol.* **1989**, *41*,

803-805) in view of Koochaki (Applicant-cited reference on IDS: EP 0 571 671 A1) is withdrawn due to the cancellation of claims. The rejection of claims 19 and 60-66 under 35 U.S.C. 103(a) as being unpatentable over Eriksen et al. (Applicant-cited reference on IDS: Eriksen, J. et al. *J. Pharm. Pharmacol.* **1989**, *41*, 803-805.) in view of Williams et al. (Applicant-cited reference on IDS: WO 02/00195 A2, January 3, 2002) is withdrawn due to the cancellation of claims. Claims 1, 13, 16, 19, 38-39, 41, 56-59, and 64-66 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 8, and 12 of U.S. Patent No. 6,387,917. The rejection is maintained. Applicant's arguments are addressed below. The rejections are modified due to Applicants' amendment to the claims 48, 49 and 68. The action is made non-final.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 13, 38, 39, 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 8, and 12 of U.S. Patent No. 6,387,917 in view of Eriksen et al. (Applicant-cited reference on IDS: Eriksen, J. et al. *J. Pharm. Pharmacol.* **1989**, *41*, 803-805.), and Watts et al. (Applicant-cited reference on IDS: WO 98/47535, October 29, 1998) and Ni et al. (U.S. 6,777, 000, effective filing date of Feb 28, 2001).

. '917 teaches a composition adapted for intranasal delivery comprising a methane sulphonate salt of an opioid analgesic, and further comprising chitosan or a salt or derivative thereof (claims 1 and 2). '917 also teaches a method of treating pain comprising administering to the nose a methane sulphonate of an opioid analgesic (claim 8), and a nasal drug delivery device containing as a drug a methane sulphonate salt of an opioid analgesic (claim 12).

'917 does not teach use of buprenorphine in the compositions or methods as the opioid analgesic.

Eriksen, Watts and Ni et al. teachings discussed as above.

It would have been obvious to a person of ordinary skill in the art at the time of invention to generate a methane sulphonate salt of buprenorphine, put it into the composition suitable for intranasal delivery taught in '917, place the composition into the nasal delivery device taught in '917, and use the composition in the method of treating pain taught in '917, to make the inventions the current application. It would have been

obvious to one of ordinary skill in the art at the time of the invention to have formulated an aqueous solution for intranasal delivery comprising 0.1-10mg/ml of buprenorphine, 5-40 mg/ml of pectin having a degree of esterification of less than 50%, which solution has a pH of 3-4.2 because of the teachings of Eriksen, Watts and Ni et al. Eriksen teaches a solution comprising the claimed amount of buprenorphine, Watts teaches the benefits of pectin with low degree of esterification in liquid formulation for delivery in mucosal surfaces and Ni et al. teaches the stability of pectins in acidic pH range (3-4). The person of ordinary skill in the art would have been motivated to use buprenorphine in the compositions and methods of '917 because '917 teaches compositions for intranasal administration which comprise analgesics generally, and buprenorphine is a well known analgesic that is administered intranasally. The person of ordinary skill in the art would have been further motivated because '917 states, this would "provide an increased absorption of the drug." (column 2, lines 66-67). The person of ordinary skill would have expected success absent evidence to the contrary. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants of the same invention.

Claims 1-15, 38, 39, 41, 48-52, 67-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-56 of co-pending application,. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants of the same invention.

Claims 1-15, 38, 39, 41, 48-52, 67-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-56 of copending Application No. 11/798,384. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants of the same invention.

The co-pending application '384 teaches an aqueous solution for intranasal administration comprising 0.1 to 10 ng/ml of buprenorphine and 5-40 mg/ml of pectin having a degree of esterification of less than 50% which solution has a pH from 3 to 4.2. The application also teaches a process of preparing the pharmaceutical solution and also teaches the use of such analgesic solutions in treating pain.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the co-pending application teaches an aqueous solution for intranasal administration comprising 0.1 to 10 ng/ml of buprenorphine and 5-40 mg/ml of pectin, a process of preparing the same and a method of treating pain administering buprenorphine analgesic solutions intranasally.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10, 12-15, 38-39, 41, 48-52, 67-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eriksen et al. (Applicant-cited reference on IDS: Eriksen, J. et al. *J. Pharm. Pharmacol.* **1989**, *41*, 803-805.), in view of Watts et al. (Applicant-cited reference on IDS: WO 98/47535, October 29, 1998) and Ni et al. (U.S. 6,777, 000, effective filing date of Feb 28, 2001).

Eriksen et al. teach an aqueous solution suitable for intranasal administration which comprises 2 mg/ml of buprenorphine as the salt buprenorphine hydrochloride. The composition of Eriksen et al. further comprises dextrose (see "The spray-device and the buprenorphine-spray solution" and "Procedure" on pp. 803-4). Due to the fact that Eriksen et al. do not add divalent metal cations into the composition during the preparation, it can be inferred that Eriksen et al. teach the composition as being substantially free of divalent metal cations. Eriksen et al. also teach a method for the preparation of said composition ("The spray-device and the buprenorphine-spray solution" on p. 803). Eriksen et al. teach a nasal delivery device loaded with said solution, wherein the nasal delivery device is a spray device ("The spray-device and the

buprenorphine-spray solution" on p. 803). Eriksen teach that buprenorphine is a μ-partial agonist opioid analgesic recommended for the treatment of moderate to severe pain (p 803, col. 1, lines 1-2) and teach administration of buprenorphine intranasally to volunteers. The reference teaches mean plasma concentration of buprenorphine ranging from 0.16 ng/ml to 1.65 ng/ml and produces a plasma concentration of 1.49 ng/ml in 20 minutes (Table 3). The reference teach a plasma concentration of 0.62 ± 0.06 ng/ml around 120 min after administration of buprenorphine (Table 3).

Eriksen et al. do not teach that the solutions comprise pectin, wherein the pectin is at a concentration of 5-40 mg/ml, 10-30 mg/ml, or 10-40 mg/ml, and wherein the pectin has a degree of esterification of less than 50%, or a degree of esterification of from 10-35%. Eriksen et al. also do not teach the solution as having a pH of from 3-4.2 or from 3.5-4.

Watts et al. teach solutions that are substantially free of divalent metal ions and which comprise therapeutic agents such as analgesic drugs such as nicotine, fentanyl (p 14, lines 22-23d pectin with a low degree of esterification for administration intranasally, and specifically wherein the degree of esterification of pectin is less than 50%, and more preferably less than 35%. The pectin is present at a concentration of from 1 to 100 mg/ml (p. 2, lines 23-26; p. 9, lines 22-27; p. 11, line 21 -p. 12, line 5; p. 12, lines 22-27; Example 1; claims 1-2). Watts et al. also teach that said solution has a pH from "2 to 9, more preferably from 3 to 8" (p.16, line 29 -p. 17, line 3). Watts et al. teach that "the lower the DE of the pectin, the lower the pH at which the composition will gel. pH may be adjusted in accordance with techniques which will be well known to

those skilled in the art" (p. 17, lines 3-6). Thus, Watts et al. suggest optimizing the pH of the composition within the disclosed preferred ranges using routine experimentation based on the pectin that is incorporated into the composition. Watts et al. also teach that the solutions comprising pectins and therapeutic agents should have a concentration of pectin greater than 4 mg/ml for solid gel formation upon intranasal administration (Example 1).

Ni et al. teaches that pectin is most stable at acidic pH levels between approximately 3-4. Below pH 3, methoxyl and acetyl groups and neutral sugar side chains are removed. Under neutral and alkaline conditions, methyl ester groups are saponified and the polygalacturonan backbone breaks through .beta.-elimination-cleavage of glycosidic bonds on the non-reducing ends of methylated Gal A residues.

It would have been obvious to a person of ordinary skill in the art at the time of invention to incorporate pectins having a low degree of esterification into the solutions of Eriksen et al., to adjust the pH of said solution to the appropriate ranges taught by Watts et al., to incorporate the solution into a spray device, and to intranasally deliver the solution in a method of inducing analgesia. The person of ordinary skill in the art would have been motivated to introduce the gelling capacity taught by Watts et al. into the solutions of Eriksen et al. because this would improve the duration of the desired plasma concentration of the active agent delivered from the compositions in the method taught by Eriksen et al. through enhanced retention of the agent in the nasal cavity. As Watts et al. teach, "It would be most beneficial, due to ease of use and of administration, to have available a simple solution spray system that was suitable for

the administration of drugs to the nose and, better still, for the drugs administered via such a system to have a long retention in the nasal cavity," (p. 2, lines 23-26). The person of ordinary skill in the art would have expected success because the mucoadhesives are designed for effecting retention of active agents in nasal spray solutions in the nasal cavity upon administration. It would have been obvious to one of ordinary skill in the art at the time of the invention to have maintained the pH of the solution comprising pectin because of Ni et al.'s teachings that pectins are stable at a pH between 3 and 4. One having ordinary skill in the art at the time of the invention would have been motivated to maintain the aqueous solution comprising pectins at a pH between 3 and 4 as claimed in order to maintain the stability of pectins at acidic pH.

Eriksen teach a plasma concentration of 0.62 ± 0.06 ng/ml around 120 min after administration of buprenorphine (Table 3). The reference does not teach maintaining the plasma concentration of buprenorphine to 0.8-5.0 ng/ml for at least 2 h.

It would have been obvious to one of ordinary skill in the art to formulate the composition comprising buprenorphine administering intranasally to produce a plasma concentration of buprenorphine to 0.8-5.0 ng/ml for at least 2 h. Eriksen teach a plasma concentration of 0.62 ± 0.06 ng/ml around 120 min after administration of buprenorphine The reference's pharmacokinetic characteristics Cmax and Tmax slightly differ from those claimed herein. However, the determination of optimal or workable pharmacokinetic characteristics by routine experimentation is obvious absent showing of criticality of the claimed characteristics. It would have been obvious to one of ordinary

skill in the art to routinely adjust the concentrations of the drug or the concentrations of the solvents or carriers to obtain the desired pharmacokinetic parameters.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eriksen et al. (Applicant-cited reference on IDS: Eriksen, J. et al. *J. Pharm. Pharmacol.* **1989**, *41*, 803-805.), in view of Watts et al. (Applicant-cited reference on IDS: WO 98/47535, October 29, 1998) as applied to claims 1-10, 12-15, 38-39, 41, 48-52, 67-71 above and further in view of Reich et al. (Reich, I., et al. "Tonicity, Osmoticity, Osmolality and Osmolarity" Remington: The Science and Practice or Pharmacy, Nineteenth Edition, Volume 1. Easton, PA: Mack, **1995**. pp. 613-615.), and Nairn (Nairn, J. G. Solutions, Emulsions, Suspensions and Extracts" Remington: The Science and Practice or Pharmacy, Nineteenth Edition, Volume 2. Easton, PA: Mack, **1995**. p. 1502).

The teachings of Eriksen and Watts et al. discussed as above.

The references do not explicitly teach the solution comprising buprenorphine has an osmolality of 0.35 to 0.5 osmol/kg.

Nairn teaches that nasal solutions are usually isotonic (p. 1502).

Reich et al. teach, "The term isotonic, meaning equal tone, is in medical usage commonly used interchangeably with isoosmotic." (p. 613). Reich et al. also teach, "Serum osmolality often is stated loosely to be about 300 mOsmol/L." (p. 615).

Although the osmolality of the intranasal solution in the instant claim 11 is slightly higher than serum osmolality, this is necessitated by the amount of pectin that is required by the teachings of Watts et al. in order that the solution gels upon intranasal administration (Example 1). Therefore, the osmolality of a solution for intranasal

administration that comprises low DE pectin as the gelling agent should be close to isoosmotic and should have the required concentration of pectin to achieve gelling upon administration as taught by Nairn, Reich et al., and Watts et al.

Response to Arguments

Regarding the rejection of claims 1-15, 38, 39, and 41 under 35 USC § 103 over Eriksen et al. (Applicant-cited reference on IDS: Eriksen, J., et al. *J. Pharm. Pharmacol.* **1989**, *41*, 803-805) in view of Watts et al. (WO 98/47535), Reich et al. (Reich, I., et al. "Tonicity, Osmoticity, Osmolality and Osmolarity" in Remington: The Science and Practice or Pharmacy, Nineteenth Edition, Volume 1. (1995) Easton, PA: Mack. pp. 613-615), and Nairn (Nairn, J. G. "Solutions, Emulsions, Suspensions and Extracts" in Remington: The Science and Practice or Pharmacy, Nineteenth Edition, Volume 2. (1995) Easton, PA: Mack. pp. 1495, 1496 and 1502), Applicants' argue that Watts provides no indication that the disclosed formulations would provide a rapid uptake of the drug. In response, Watts has been cited to show that liquid pharmaceutical compositions comprising a therapeutic agent and a pectin with a low degree of esterification for administration to a mucosal surface can be formulated. Watts has been added to show that addition of pectins with a low degree of esterification may be formulated in pharmaceutical solutions to apply as such which will gel upon or just after, application to mucosa. Eriksen teach a formulation of solution comprising buprenorphine with the same claimed concentration. The rapid uptake of the drug are inherent properties of the formulations suggested by Eriksen et al. in view of Watts et al. as the combined teachings of Eriksen, Watts et al. teach the formulation comprising the

claimed concentrations of buprenorphine and pectin and further Ni et al. teach the benefits of acidic pH (3-4 for pectins stabiltiy). Applicants' argue that one of ordinary skill in the art would glean from Watts that the absorption will be controlled to give a flatter profile. In response, as stated above, Watts has been cited to show the advantages of adding pectin in liquid formulations for intranasal administration. Applicants' arguments regarding the pH of the solution have been fully considered but are moot in view of new rejections presented in this action.

Regarding the rejection of claims 1, 13, 16, 19, 38-39, 41, 56-59, and 64-66 on the ground of nonstatutory obviousness-type double patenting over claims 1-2, 8, and 12 of U.S. Patent No. 6,387,917, Applicant argues that there is no teaching of "formulations for the nasal cavity that comprise buprenorphine and pectin in the claimed concentrations, which solution has a pH of 3-4.2. It would have been obvious to a person of ordinary skill in the art at the time of invention to generate a methane sulphonate salt of buprenorphine, put it into the composition suitable for intranasal delivery taught in '917, place the composition into the nasal delivery device taught in '917, and use the composition in the method of treating pain taught in '917, to make the inventions the current application. It would have been obvious to one of ordinary skill in the art at the time of the invention to have formulated an aqueous solution for intranasal delivery comprising 0.1-10mg/ml of buprenorphine, 5-40 mg/ml of pectin having a degree of esterification of less than 50%, which solution has a pH of 3-4.2 because of the teachings of Eriksen, Watts and Ni et al. Eriksen teaches a solution comprising the claimed amount of buprenorphine, Watts teaches the benefits of pectin with low degree

of esterification in liquid formulation for delivery in mucosal surfaces and Ni et al. teaches the stability of pectins in acidic pH range (3-4). The person of ordinary skill in the art would have been motivated to use buprenorphine in the compositions and methods of '917 because '917 teaches compositions for intranasal administration which comprise analgesics generally, and buprenorphine is a well known analgesic that is administered intranasally. The person of ordinary skill in the art would have been further motivated because '917 states, this would "provide an increased absorption of the drug." (column 2, lines 66-67). The person of ordinary skill would have expected success absent evidence to the contrary. Thus the double-patenting rejection is properly maintained.

Any rejection of record not addressed herein is withdrawn.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to UMAMAHESWARI RAMACHANDRAN whose telephone number is (571)272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617